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Adhesives

To assure their safe use in pharmaceutical drug delivery and wound applications, pressure-sensitive adhesive products are manufactured, packaged and tested at the Healthcare Industries Manufacturing Site, utilizing principles of cGMP regulations for Active Pharmaceutical Ingredients (APIs).

Regulatory Status

Tested for USP Class VI's

FDA Material Application

European Technical

and FDA Drug Master File

Description

Solvent based non-sensitizing
transdermal pressure-
sensitive adhesive
formulations

Typical Applications

* Adhesion of dressings,
prosthetics and other
devices to the body

Pressure Sensitive Adhesives

Dow Corning * MD745-2 Silicone
Adhesive

Dow Corning * MD746-2 Silicone
Adhesive

Customizable Pressure Sensitive Adhesives for Transdermal Delivery Systems

BIO-PSA * 43+ Series

BIO-PSA * 42+ Series

BIO-PSA * 41+ Series

Aqueous compatible adhesive in
solvent, custom formulation,
adhesive solvent selection

* Skin adhesion of
transdermal drug delivery
systems, specifically
designed for compatibility
with non-sterile drug
drugs

Custom adhesive formulations
in solvent

* Skin adhesion of
transdermal drug delivery
systems to the body

BIO-PSA * 40+ Series

BIO-PSA * 45+ Series

BIO-PSA * 44+ Series

Solventless adhesive in
formulation with no solvents
lack custom formulation

* Skin adhesion of
transdermal drug delivery
systems to the body

BIO-PSA * Hot Melt Adhesive

Dow Corning has a wide range of products available for use as medical device components.

Regulatory Status

For more information on regulatory status, please contact your local sales representative.

Description

Two-part, platinum-catalyzed adhesive formulated for use as a medical device component.

Typical Applications

* Clear and soft skin adhesive for wound dressing and pharmaceuticals; topical or transdermal applications.

Soft Skin Adhesive

Flow Coating 1-708-A&B

Product Information

Healthcare Industries

DOW CORNING

Dow Corning[®] MD7-4502 Silicone Adhesive *Dow Corning*[®] MD7-4602 Silicone Adhesive

FEATURES

- Pressure sensitive adhesive
- Nonsensitizing
- Nonirritating

Nonsensitizing, pressure sensitive adhesives

APPLICATIONS

Dow Corning[®] MD7-4502 and MD7-4602 Silicone Adhesives may be used where a nonsensitizing adhesive is needed to adhere dressings, prosthetic and other metal or plastic devices to the body. Known applications include:

- Adhering ileostomy and colostomy appliances to the skin
- Attaching appliances to the skin for patient monitoring
- Affixing surgical dressings and pads to the skin
- Adhering external prosthetic devices
- Hairpiece adhesion

TYPICAL PROPERTIES

Specification Writers: Please contact your local Dow Corning sales office or your Global Dow Corning Connection before writing specifications on this product.

Method	Test	Unit	Result	
			MD7-4502	MD7-4602
CTM [®] 0086	Solid Content	percent	65	60
	Nominal Tack Value		Medium	High
	Peel Adhesion	g/cm	700	500
	Shear	kg/6.25 cm ²	16	15
CTM 0006	Flash Point	°C (°F)	-4.4 (24.1)	-4.4 (24.1)
	Solvent		Ethyl Acetate	Ethyl Acetate
CTM 0001A	Specific Gravity at 25 °C (77 °F)		1.02	1.02
CTM 0050	Viscosity	mPa·s	2500	3000
	Rheology Eta at 0.01 rad/sec at 30 °C (86 °F) - P		5 x 10 ⁻³	5 x 10 ⁻³

CTMs (Corporate Test Methods) correspond to standard ASTM tests in most instances. Copies of CTMs are available upon request.

DESCRIPTION

Dow Corning MD7-4502 and MD7-4602 Silicone Adhesives are nonsensitizing pressure sensitive adhesives specifically designed for adhering medical devices to the body. Specific advantages of these products include:

- Adhesion to many surfaces
- Retained adhesive properties in the presence of moisture or perspiration, under normal temperature variations
- Excellent permeability to moisture and gasses
- Long lasting, non-gumming and non-peeling characteristics

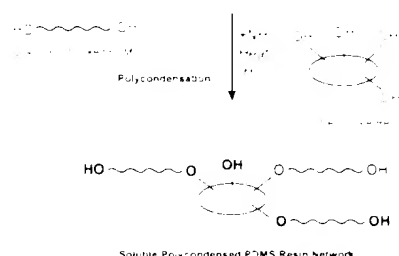
IMPORTANT NOTE

The purchaser should understand the limited warranty described herein and thoroughly test products made in part or otherwise with *Dow Corning* MD7-4502 Silicone Adhesive or *Dow Corning* MD7-4602 Silicone Adhesive to determine the acceptability of the product's performance in a specific application.

SYNTHESIS AND STRUCTURE

Dow Corning MD7-4502 and MD7-4602 Silicone Adhesives are products of the condensation of a silanol

endblocked polydimethylsiloxane (PDMS) with a silicate resin as shown:



BIOCOMPATIBILITY

Biocompatibility tests, which meet or exceed current USP Class VI Plastics Tests, and which have been performed on the solids found in *Dow Corning* MD7-4502 and MD7-4602 Silicone Adhesives, are shown in Table I.

Adhesive solids were further evaluated for acute effects using direct application of adhesive and adhesive solids. The material did not produce skin irritation when applied to the skin of albino rabbits.

A cumulative skin irritation test in humans was also performed with *Dow Corning* MD7-4502 and MD7-4602 Silicone Adhesives. The results

of the test indicated that the product was not a primary skin irritant. There was also no evidence that the product possessed skin fatiguing properties. A separate human repeat insult patch test indicated that the solids did not cause skin sensitization.

Every production lot of adhesive is tested for the absence of cytopathic effects using a tissue cell culture test (direct contact method).

MANUFACTURING ENVIRONMENT

Dow Corning MD7-4502 and MD7-4602 Silicone Adhesives are manufactured, tested and packaged under strict quality control guidelines at the Healthcare Industries Materials Site (HIMS). The HIMS (Hemlock, Mich.) is dedicated to the production of silicone materials for healthcare applications. It is registered with the U. S. Food and Drug Administration (FDA) as a drug establishment (CFR 1816403). The site quality system for active pharmaceutical ingredients (APIs) is in compliance with current Good Manufacturing Practices for Bulk Pharmaceutical Products. The site is also ISO registered by BSI.

HOW TO USE

How to Apply

Apply the liquid adhesive to clean substrates and allow the solvent to *fully evaporate* before contact with the skin is made.

Removal

From the skin: When removing *Dow Corning* MD7-4502 or MD7-4602 Silicone Adhesives from the skin, either *Dow Corning*® Q7-9180 Silicone Fluid (1 mm² s viscosity) or USP isopropyl alcohol is recommended.

From other surfaces: When removing *Dow Corning* MD7-4502 or MD7-4602 Silicone Adhesives from substrates other than skin, *Dow Corning* Q7-9180 Silicone Fluid (1 mm² s viscosity), isopropyl alcohol, ethyl acetate or heptane is recommended. Some of these solvents may cause skin irritation and are highly flammable. They may also deteriorate certain substrates, such as some plastics, and should be used with appropriate precautions.

Note that organic solvents may cause irritation and are flammable; appropriate precautions should be taken. When removing *Dow Corning* MD7-4502 or MD7-4602 Silicone Adhesive from a substrate, and more particularly from skin, apply the appropriate solvent liberally to a clean cloth or gauze pad and wipe the surface clean. Reapplication may be necessary if the residual adhesive layer is heavy.

Table I: Biocompatibility

Test	Results
Cytotoxicity (<i>in-vitro</i>)	Non-cytopathic effects
Irritation	Nonirritating
Sensitization	Nonsensitizing
Subacute Toxicity USP Class V Extractables	No difference between extract and control
90-Day Implant	Equivalent response between control and test material

A cottonseed oil extract tested positive in one test, but in a separate test, no reaction was detected.

Precautions

The solvent carrier (ethyl acetate) in *Dow Corning* MD7-4502 and MD7-4602 Silicone Adhesives is a flammable liquid with a low flash point (-4.4 °C/24.1°F), and must be handled with care. Avoid handling the product near open flame or heat sources. Bond or ground containers to prevent static electrical discharge.

- Solvent causes eye irritation; avoid contact with eyes.
- May cause respiratory tract irritation; use with adequate ventilation and keep container closed with not in use. Avoid breathing vapor.
- May be harmful if swallowed; not for internal use.

HANDLING PRECAUTIONS

PRODUCT SAFETY INFORMATION REQUIRED FOR SAFE USE IS NOT INCLUDED IN THIS DOCUMENT. BEFORE HANDLING, READ PRODUCT AND MATERIAL SAFETY DATA SHEETS AND CONTAINER LABELS FOR SAFE USE, PHYSICAL AND HEALTH HAZARD INFORMATION. THE MATERIAL SAFETY DATA SHEET IS AVAILABLE FROM YOUR DOW CORNING REPRESENTATIVE, OR DISTRIBUTOR, OR BY CALLING YOUR GLOBAL DOW CORNING CONNECTION.

USABLE LIFE AND STORAGE

When stored at or below 25°C (77°F) in the original, unopened containers, *Dow Corning* MD7-4502 and MD7-4602 Silicone Adhesives have a shelf life of 72 months from the date of manufacture.

Dow Corning will guarantee the shelf life of these products until the date indicated on the label, if stored in appropriate conditions.

PACKAGING

Dow Corning MD7-4502 and MD7-4602 Silicone Adhesives are supplied in 16- and 180-kg (35- and 397-lb) containers, net weight.

SHIPPING LIMITATIONS

Dow Corning MD7-4502 and MD7-4602 Silicone Adhesives contain a flammable solvent. Refer to product packaging and MSDS for additional information.

HEALTH AND ENVIRONMENTAL INFORMATION

To support customers in their product safety needs, Dow Corning has an extensive Product Stewardship organization and a team of Health, Environment and Regulatory Affairs specialists available in each area. For further information, please consult your local Dow Corning representative.

ORDERING INFORMATION

To order these products, contact your local Dow Corning Sales Representative or call Dow Corning at +33 (0) 4 92 94 40 00.

Note: Before the first shipment of material, Dow Corning will request that the user signs the PSDS as the confirmation that it has been received, read and understood.

LIMITED WARRANTY INFORMATION – PLEASE READ CAREFULLY

The information contained herein is offered in good faith and is believed to be accurate. However, because conditions and methods of use of our products are beyond our control, this information should not be used in substitution for customer's tests to ensure that Dow Corning's products are safe, effective, and fully satisfactory for the intended end use. Suggestions of use shall not be taken as inducements to infringe any patent.

Dow Corning's sole warranty is that the product will meet the Dow Corning sales specifications in effect at the time of shipment. Your exclusive remedy for breach of such warranty is limited to refund of purchase price or replacement of any product shown to be other than as warranted.

DOW CORNING SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR MERCHANT ABILITY. DOW CORNING DISCLAIMS LIABILITY FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES.

